

# Mediprene® 500484M

Thermoplastic Elastomer

ELASTO

## Message:

ELASTO have developed a range of Mediprene thermoplastic elastomers (TPE) for plunger seals in single-use syringes. The TPE seal, which is mounted on the end of the plunger, needs to provide a leakproof seal with the syringe barrel. As ease of use for the medical practitioner and patient comfort are also key requirements, the seal helps to optimize plunger movement for accurate dosage control and ease of injection.

Regulatory compliance

Originating from medical raw materials with high biocompatibility status and compounded under clean conditions, Mediprene TPEs are the material of choice for medical customers who want to maximize the probability that their devices will pass relevant medical tests.

The raw materials in these compounds comply with food contact norms like FDA 21CFR and 2011/10 EC. All polymers used have passed tests according to USP class VI and the paraffinic oil has passed the USP Mineral Oil NSF H1, reg 125038 and also the European Pharmacopeia, liquid paraffin.

Mediprene TPEs are latex free, which reduces the risk of allergic reactions. Representative grades have passed cytotoxicity tests according to ISO 10993-5 and biocompatibility tests according to USP Class VI.

General Information			
Features	Biocompatible		
	Food Contact Acceptable		
Uses	Medical/Healthcare Applications		
Agency Ratings	EU 2011/10/EC		
	FDA Unspecified Rating		
	ISO 10993 Part 5		
	USP Class VI		
Appearance	Colors Available		
	Translucent		
Processing Method	Extrusion		
	Injection Molding		
Physical	Nominal Value	Unit	Test Method
Specific Gravity	0.880	g/cm <sup>3</sup>	ASTM D792
Melt Mass-Flow Rate (MFR) (190°C/2.16 kg)	1.0	g/10 min	ASTM D1238
Hardness	Nominal Value	Unit	Test Method
Durometer Hardness (Shore A, 4.00 mm)	48		ASTM D2240
Mechanical	Nominal Value	Unit	Test Method
Tensile Strength			ASTM D638
--	9.90	MPa	
100% Strain	1.20	MPa	
300% Strain	1.90	MPa	
Tensile Elongation (Break)	800	%	ASTM D638

Elastomers	Nominal Value	Unit	Test Method
Tear Strength	18.0	kN/m	ASTM D624

Injection	Nominal Value	Unit
Rear Temperature	180 to 220	°C
Middle Temperature	180 to 220	°C
Front Temperature	180 to 220	°C
Mold Temperature	20.0 to 50.0	°C

Extrusion	Nominal Value	Unit
Cylinder Zone 1 Temp.	150 to 210	°C
Cylinder Zone 2 Temp.	150 to 210	°C
Cylinder Zone 3 Temp.	150 to 210	°C
Cylinder Zone 4 Temp.	150 to 210	°C
Cylinder Zone 5 Temp.	150 to 210	°C

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